REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claims 12 and 21 have been amended to clarify the features questioned by the Examiner on page 3 of the Office Action.

Accordingly, the rejection of claims 12 and 21-23 under 35 U.S.C. 112, second paragraph, is believed to be overcome.

Claims 1-2, 7-12 and 15 are rejected under 35 U.S.C. 102 as anticipated by U.S. 2005/0181052 ('052). This ground of rejection is respectfully traversed.

The capsule disclosed in '052 reference is limited to a gelatin capsule (see 0063 paragraph). The Examples of '052 reference disclose only the use of hard gelatin capsules (see 0069 paragraph).

It should be noted that the capsule preparation of the present invention does not use a hard gelatin capsule.

As seen from pages 1-3 of the Background Art section of the present specification, in the case of a capsule preparation which is common in the prior art containing a compound unstable to water such as a benzimidazole type compound, there is a problem that a commonly used hard gelatin capsule has weak mechanical strength in a low moisture state and is apt to be broken.

On the other hand, in a preparation containing a compound unstable to water, typically, a benzimidazole type compound, it is desired to lower the moisture content of the preparation per se to improve stability. Then, a capsule into which such a preparation is filled should have good mechanical strength even at a low moisture state.

Under these circumstances, the present invention provides "a capsule preparation, which comprises a medicine unstable to moisture, is stable in a low moisture state and has pH-independent disintegration properties" (claim 1). Therefore, it is clear that the above hard gelatin capsule, or a HPMC capsule which has a problem that solubility is low at low pH (see the Background Art section of the present specification), is excluded from the present invention.

The Examiner states as follows:

"The composition (a capsule preparation) taught by '052 is stable in a low moisture state. This argument is supported by the wet granulation step." (page 4, middle of the 1st paragraph of the Official Action).

However, the disclosure pointed out by the Examiner of the '052 reference is directed to the production of granules to be filled in the capsule. The '052 reference does not teach or suggest any solution to such a problem of a hard gelatin capsule, in that a hard gelatin capsule has weak mechanical strength in a low moisture state and is apt to be broken.

As seen from Experiment Example 1, on pages 83-84 of the present specification, the fracture ratio of gelatin capsules is very high. Thus it is clear that a hard gelatin capsule is excluded from the present invention. Thus, '052 reference do not bar the novelty of the present invention.

Accordingly, this ground of rejection is believed to be overcome.

Claims 4 and 16-24 are rejected under 35 U.S.C. 103 as unpatentable over '052. This ground rejection is respectfully traversed.

That is, claims 1-6 of the present application refer to the components of the capsule itself. In this respect, the Examiner has mistakenly confused components of the capsule itself with components i.e. the contents of the capsule.

More specifically, regarding claim 4, the Examiner states as follows:

". . . The capsule preparation disclosed by '052 further comprises a lubricant, optionally one or more excipients, and an enteric coating, wherein the weight ratio of lansoprazole to lubricant is from about 1:4 to about 8:1, respectively. Preferred, not-limiting, examples of excipients include microcrystalline cellulose, maltodextrin, starch, and various cellulose derivatives. All of the above excipients are polysaccharides." (see page 7, the 1st paragraph)

However, the polysaccharide claimed in claim 4 defines the main component of the capsule, not the contents to be filled in the capsule. As mentioned above, '052 reference do not teach or suggest the capsule preparation of the present invention.

In view of the foregoing, favorable reconsideration and withdrawal of this ground of rejection is solicited.

Lastly, claim 5 is rejected under 35 U.S.C. 103 as unpatentable over '052 in view of U.S. 5,665,348. This ground of rejection is respectfully traversed.

Regarding pullulan of claim 5, the Examiner has cited US 5665348. However, this reference discloses pullulan as a component of the contents to be filled in a capsule. There is no teaching or suggestion of a pullulan capsule in this reference.

Even if this reference is combined with '052 reference, they do not teach or suggest the present invention.

In view of the foregoing, it is believed that each rejection set forth in the Official Action has been overcome, and that the application stands in condition for allowance. Accordingly, such allowance is solicited.

Respectfully submitted,

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